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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,600	09/15/2000	Jean-Baptiste Dumas Milne Edwards	31.US3.CIP	2172

7590 07/30/2002  
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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/663,600

Applicant(s)

EDWARDS ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,4,12 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,12 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16, 17, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 18 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 2,4,12 and 15-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 2, 4, 12, and 15-21 are pending in the instant application. Claims 1, 3, 5-11, 13 and 14 have been canceled and claims 16-21 have been added as requested by Applicant in Paper Number 12, filed May 20, 2002.

### ***Election/Restrictions***

2. Applicant's election of Group B, drawn to polypeptides of SEQ ID NO: 186 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, 4, 12 and 15 are withdrawn as being drawn to a non-elected invention.

Claims 16-21 are currently under examination.

### ***Priority***

3.1 This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent application 09/191,997. A statement reading "(now abandoned)" should be included after "09/191,997 filed 13 November 1998" following the title of the invention.

3.2 For purposes of establishing the effective priority date, the filing date of the parent application, 09/191,997 filed 13 November 1998, is considered the priority date. The provisional applications were examined to determine if the protein of SEQ ID NO: 186 was present in any of the provisionals, and it could not be established that the protein was disclosed in any of the

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provisionals, because the numbering of the sequences appears to be different from that of the instant application. For example, in provisional 60/069,957, SEQ ID NO: 186 is a nucleic acid sequence and not a protein sequence as in the instant application, and it also encodes a different protein from the protein of SEQ ID NO: 186 of the instant application. Applicant is requested to identify which provisionals, if any, contain the protein and encoding nucleic acid sequences and to identify what the SEQ ID NOS: are in those applications that correspond to the instant invention.

#### ***Information Disclosure Statement***

4. The substitute for form PTO-1449 filed May 20, 2002 is present in the file, and the references submitted with parent application 09/191,997 were considered. However, the additional references submitted with the instant application are not with the file and have not been found in the IDS storage facility. Therefore it is requested that Applicants submit a copy of the references for consideration with their response to this Office Action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 18 and 21 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO: 186, identified as Claudin-50, which is shown to have the activity of binding Clostridium enterotoxin (CE) (page 121 of specification). However, the claims as written include polypeptides comprising homologues, encompass polypeptides that vary substantially in length and also in amino acid composition. The instant disclosure of a single polypeptide, that of SEQ ID NO: 186 with the instantly disclosed specific activity, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

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An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide sequence SEQ ID NO: 186, which is a 230 amino acid protein, having a signal sequence from amino acid -24 to -1, and a mature protein sequence from amino acid 1 to 206. The claims encompass, however, any protein that comprises the signal sequence of SEQ ID NO: 186, with no structural or functional requirements for the rest of the protein. The signal sequence, which is presumably proteolytically cleaved to result in mature protein, does not have the activity of binding Clostridium enterotoxin, and the specification has not described any other protein having this signal sequence that also has the function of binding CE. Given the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim. No activity is set forth for the additional sequences, and the specification has not taught the skilled artisan how to use a protein that does not bind CE. There is no correlation or nexus provided between possession of the signal

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sequence and the encompassed functional features of SEQ ID NO: 186 such that it is clearly conveyed that possession of any polypeptide having this structural region in common would possess these functional features. Further, even if the proposed consensus sequence were definitive of a genus with a specified function, the instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polypeptides encompassed.

### ***Conclusion***

6.1 Claims 16, 17, 19 and 20 are allowed.

6.2 Claims 18 and 21 are rejected.

The art considered pertinent to the present application is Baker et al., WO 20/0012708, March 9, 2000, and Yue et al., WO 20/0018915, April 6, 2000, both cited by Applicant, which disclose polypeptides (Fig. 78 for Baker et al. and pages SEQ ID NO: 3 for Yue et al.) that are 100% identical to the polypeptide of SEQ ID NO: 186 of the instant specification (see attached sequence alignments). These references are not considered prior art, since the effective filing date of the instant application is before the publication dates of the references.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.


Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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